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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,609	01/25/2000	Roderick T. Bunch	SO-3170	7385

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	22

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.	Applicant(s)
09/490,609	Bunch et al
Examiner	**Art Unit**
Jane Zara	1635

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Dec 9, 2002* .

2a) ☐ This action is **FINAL.** 2b) X This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *25-28 and 31-35* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *25-28 and 31-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐	Notice of References Cited (PTO-892)	4) ☐	Interview Summary (PTO-413) Paper No(s).
2) ☐	Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐	Notice of Informal Patent Application (PTO-152)
3) ☐	Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) ☐	Other:

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-09-02 has been entered.

Applicants' response and amendments filed August 2, 2002 and December 9, 2002, Paper Nos. 17 and 21 respectively, have been received and entered.

Any rejections not repeated in this Office action are hereby withdrawn.

Response to Arguments and Amendments

Maintained Rejections

Claims 32 and 34 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action mailed August 13, 2001 and May 21, 2002, Paper Nos. 12 and 15, respectively.

Applicant's arguments filed August 2, 2002 have been fully considered but they are not persuasive. Applicants argue that the instant claims are enabled over the full scope claimed and furthermore that such enablement does not require undue experimentation. Contrary to Applicants' assertions, the ability to measure the carcinogenicity of any composition in any cell of

any organism following exposure to a suspected carcinogen by determining the presence or absence of mRNA which hybridizes to SEQ ID Nos: 280, 317, 384, 465 or 488 requires undue experimentation beyond that which has been provided in the instant disclosure. The specification teaches the in vitro detection of ten differentially expressed nucleic acids (via nucleic acid hybridization assays) in rat liver cells following exposure of rats to phenobarbital. This is not representative or correlative of the ability to detect carcinogenicity of compositions in any and/or all cells in any organism following the organism's exposure to a suspected carcinogen. The example in rat liver cells of differential gene expression following phenobarbital exposure does not accurately predict (or enable one to accurately predict) the over expression or under expression of such marker genes in a different cell type following exposure to any and/or all carcinogens in an organism. Therefore, the rejection for lacking enablement over the broad scope claimed is maintained.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28, 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25, lines 3 and 12, the term "under conditions permitting nucleic acid hybridization" is vague and unclear (e.g. perhaps --specific-- can be inserted into the claim before "nucleic acid").

In claim 25, line 7, it is unclear how a complementary nucleic aicd molecule willhybirdize with the target nucleic aicd molecule (i.e. perhaps "complementary nucleic acid molecule" should be changed to "nucleic acid molecule").

In claim 31, lines 5-6, claim 32, line 5, the term "substantially hybridizes" is vague and unclear. Appropriate clarification is requested.

In claim 31, line 5, and claim 32, line 4, "determining" does not set forth a positive step (i.e. perhaps "determining" should be replaced by --detecting--).

In claims 32, lines 4-5, and claim 35, lines 1-2, it is unclear how a test mammal comprises a rat hepatocyte. It is also unclear how mRNA hybridization occurs in a rat hepatocyte in a test mammal (i.e. perhaps a step for obtaining the mRNA from a cell in a test mammal, prior to hybridization, should be inserted into the claimed method).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al.

Hillman et al disclose diagnostic methods comprising measuring the presence or absence of biomarker gene expression for carcinogenesis comprising measuring a difference in the expression pattern of SEQ ID NO: 317 in rat and human cells in vitro (See especially col. 1-2 and 15-19; figure 2 and the accompanying sequence alignments).

Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Upton et al.

Upton et al disclose the differential expression of the biomarker mRNA of SEQ ID NO: 465 in cancer (leukemic) cells. Upton et al teach changes in the expression pattern of SEQ ID. NO: 465, which comprises a tyrosine phosphorylation site for a transforming gene product of the carcinogenic Rous sarcoma virus (See entire document, especially the second paragraph of the introduction and the first paragraph of the experimental section on page 425; See the accompanying sequence alignments).

Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al.

Lee et al disclose the differential expression of the biomarker mRNA of SEQ ID NO: 384 in various differentiated and undifferentiated cells in vitro, whereby a comparison of gene expression is correlated with the effects of toxic compounds on gene expression and cancer progression (See entire document, especially figure 1 on page 8305 and the last paragraph on page 8307; See accompanying sequence alignments).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ram R. Shukla

RAM R. SHUKLA
PATENT EXAMINER

JZ

February 23, 2003